

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA
ex rel. MELAYNA LOKOSKY,

Plaintiff-Relator,

v.

ACCLARENT, INC., ETHICON, INC., and
JOHNSON & JOHNSON,

Defendants

11 CA 11217 WGY

CIVIL ACTION NO.

C.A. No.

FILED UNDER SEAL
PURSUANT TO 31 U.S.C.
§ 3730(b)(2)

MAGISTRATE JUDGE *Dollings*

COMPLAINT

PLAINTIFF-RELATOR DEMANDS A TRIAL BY JURY ON ALL COUNTS

Plaintiff-Relator Melayna Lokosky ("Relator") hereby files this complaint against
Acclarent, Inc., Ethicon, Inc., and Johnson & Johnson, ("Defendants"), and states as follows:

INTRODUCTION

1. This action concerns false and fraudulent Medicare and Medicaid reimbursement claims for the surgical use of Acclarent's medical device—the Relieva Stratus MicroFlow Spacer. For several years, Acclarent has been defrauding Medicare and Medicaid by bringing this product to market, and the company continues to do so. The fraud has caused these and other federal programs to pay for devices that were: (a) only on the market because of Acclarent's false statements to the FDA; (b) misbranded; (c) medically unnecessary; (d) used by physicians as a direct result of Acclarent's marketing for unproven, off-label uses; and (e) fraudulently used and billed in a manner intentionally calculated to increase the amount of reimbursement paid by the government to doctors and hospitals, thus increasing Acclarent's product sales, without any greater benefit to patients.

2. The Relator was an employee of Acclarent and attempted to halt these off-label and fraudulent practices. For her efforts, Acclarent retaliated against her and terminated her employment.

PARTIES

3. Plaintiff-Relator Melayna Lokosky is an individual who resides in Scottsdale, Arizona. Prior to her retaliatory termination, she was employed by Acclarent as a sales representative.

4. Defendant Acclarent, Inc. ("Acclarent") is a Delaware corporation with a principal place of business in Menlo Park, California. Acclarent is a manufacturer of medical devices and supplies and regularly sells its products in the Commonwealth of Massachusetts and maintains full time employees within the Commonwealth. In January 2010, Acclarent was acquired by Defendant Ethicon, Inc., a wholly owned subsidiary of Defendant Johnson & Johnson.

5. Defendant Ethicon, Inc. ("Ethicon") is a New Jersey corporation with a principal place of business in Somerville, New Jersey. Ethicon is a medical supply company that regularly distributes, markets, and sells products in the Commonwealth of Massachusetts and maintains full time employees within the Commonwealth. In January 2010, Ethicon acquired Acclarent and is legally responsible for all of Acclarent's liabilities before and after the acquisition. Ethicon is a wholly owned subsidiary of Defendant Johnson & Johnson.

6. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with a principal place of business in New Brunswick, New Jersey. J&J is a manufacturer, distributor, and seller of drugs, devices, medical supplies, and hygiene products. J&J regularly distributes, markets, and sells products in the Commonwealth of Massachusetts and maintains full time

employees within the Commonwealth. In January 2010, J&J, through its subsidiary, Ethicon, acquired Acclarent and is legally responsible for all of Acclarent's liabilities before and after the acquisition.

JURISDICTION AND VENUE

7. Pursuant to 28 U.S.C. § 1331, this District Court has original jurisdiction over the subject matter of this civil action since it arises under the laws of the United States, in particular the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* In addition, the FCA specifically confers jurisdiction upon the United States District Court. 31 U.S.C. § 3732(b). This court has supplemental and diversity jurisdiction over Relator's state law claims.

8. This District Court has personal jurisdiction over the Defendant pursuant to 31 U.S.C. § 3732(a) because the FCA authorizes nationwide service of process and the Defendant has sufficient minimum contacts with the United States of America.

9. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because Defendants transact business in this judicial district.

10. The Relator is unaware of any public disclosure of the information or allegations that are the basis of her complaint. In the event that there has been a public disclosure, the Relator is the original source of the information and allegations contained in this complaint. Prior to the filing of this action, Relator voluntarily provided the information to the United States Government, having discussed her allegations with the United States on or before July 6, 2011.

FACTUAL ALLEGATIONS

I. SUMMARY OF CASE

11. This case concerns the Relieva Stratus MicroFlow Spacer, a set of products developed and marketed by Acclarent.

12. In order to receive 510(k) clearance for the MicroFlow Spacer, Acclarent lied to the FDA about the device's intended use and its similarity to previously cleared products. Although the FDA cleared the device as an inert, non-drug delivering spacer to be placed in a patient's ethmoid and frontal paranasal sinuses for no more than 14 days as a healing aid, Acclarent's intended use for the MicroFlow Spacer is and always was to deliver the steroid Kenalog-40 in an unproven and off-label manner for 30 days or longer.

13. By concealing the MicroFlow Spacer's true drug delivery purpose from the FDA, Acclarent easily obtained 510(k) clearance for the device within months of submitting its application, thereby avoiding the most stringent level of FDA review for a medical device—the premarket approval (“PMA”) review. PMA reviews require clinical trial data submission demonstrating a device's safety and efficacy. This process can take years, first to complete the studies, and then for the FDA to review the data and issue its approval. And the FDA would not have issued a PMA approval for the MicroFlow Spacer, because Acclarent did not (and still does not) possess any supporting clinical data. Quite the opposite, Acclarent has known for years that the MicroFlow Spacer loaded with Kenalog-40, a corticosteroid approved only for injection in joints or muscle tissue, provided no additional benefits. It even amended the protocol of its lone study midstream to remove collection of data that confirmed this. Had Acclarent been truthful with the FDA, the MicroFlow Spacer would have never been on the market.

14. But Acclarent was not truthful with the FDA, and the FDA cleared the device as a result. Once cleared, Acclarent never marketed the MicroFlow Spacer for the intended use conveyed to the FDA. Instead, Acclarent directed doctors at ENT (ear, nose, and throat) surgical centers to use the MicroFlow Spacer for its true intended use—with off-label Kenalog-40 for more than 14 days.

15. This marketing was off-label for three reasons. First, the FDA never approved the MicroFlow Spacer as a drug-eluting or drug delivery device, and its use could not exceed 14 days. Second, the FDA never approved Kenalog-40 for post-surgical, topical, paranasal sinus use. Use around the eyes, in fact, carries a risk of blindness and other complications. Finally, marketing the combination of the MicroFlow Spacer with Kenalog-40 was off-label because such combinations, even if sold separately, required a *de novo* FDA review under the 1990 Safe Medical Devices Act. By concealing the intended combination of device and drug from the FDA in order to get clearance, and then uniformly marketing that very same off-label combination to hospitals and physicians, Acclarent caused the MicroFlow Spacer to be misbranded, and thus ineligible for any federal reimbursement.

16. The MicroFlow Spacer is not an implant and such use is not medically necessary. Yet Acclarent successfully coached doctors and hospital staff to fraudulently code the MicroFlow Spacer as an implant for the lone purpose of increasing federal government reimbursement. This coaching resulted in claims for reimbursement to Medicare and Medicaid that were either medically unnecessary or unnecessarily inflated. And it also resulted in higher profits to physician and hospitals, as well as increased sales to Acclarent.

17. In December 2009, Johnson & Johnson announced that it, through its subsidiary Ethicon, was acquiring Acclarent for \$785 million in cash. The acquisition became final in January 2010. Johnson & Johnson immediately became concerned about the off-label marketing of the MicroFlow Spacers and announced two months later that it would cease all active marketing of the product due to regulatory concerns. Despite the announcement, J&J still manufactured, sold, and distributed the product. The product was available in Acclarent's product catalogue. Sales representatives were allowed to discuss the product and were even

given incentives to do so. And hospitals that had already been placing orders prior to the announcement as result of the off-label marketing could still re-order the product. Even hospitals that had never ordered the product before could easily order it through the catalogue, which is available on the internet.

18. J&J never took any actions to mitigate damages. It never corrected the false and fraudulent statements that Acclarent made to the FDA. It never retracted or corrected the false and fraudulent statements made to doctors and hospitals about the MicroFlow Spacer's proper use. It never retracted or corrected the false statements of medical necessity for using the product with Kenalog-40 and for more than 14 days. It never removed the product from the market. And it never terminated the employees who made false statements to the FDA or who devised the plan to market the product off-label.

19. As a result of the conduct described above, the United States government, through various federal programs, has paid roughly \$30 million and continues to pay and reimburse for products which are misbranded, not medically necessary, were only cleared for marketing because of fraud, and whose use is caused by off-label marketing.

II. THE PURCHASE OF PRESCRIPTION DEVICES BY FEDERAL AND STATE GOVERNMENTS

20. Medicaid is a joint program of the United States government and state governments to provide medical services, including prescription devices, to persons who could not otherwise afford them. All of the States and the District of Columbia participate in Medicaid and use state or district funds for the purchase of medical devices, along with the proportional federal funds they receive through the program.

21. The United States also purchases prescription devices through a number of other programs. Medicare is a social insurance program administered by the United States

government, providing health insurance coverage to people who are aged 65 and over. Medicare also provides coverage to those who are disabled and have been receiving either Social Security benefits or the Railroad Retirement Board disability benefits for at least 24 months, who receive dialysis for end stage renal disease or need a kidney transplant, or who have amyotrophic lateral sclerosis ("Lou Gehrig's disease") and are eligible for Social Security Disability Insurance.

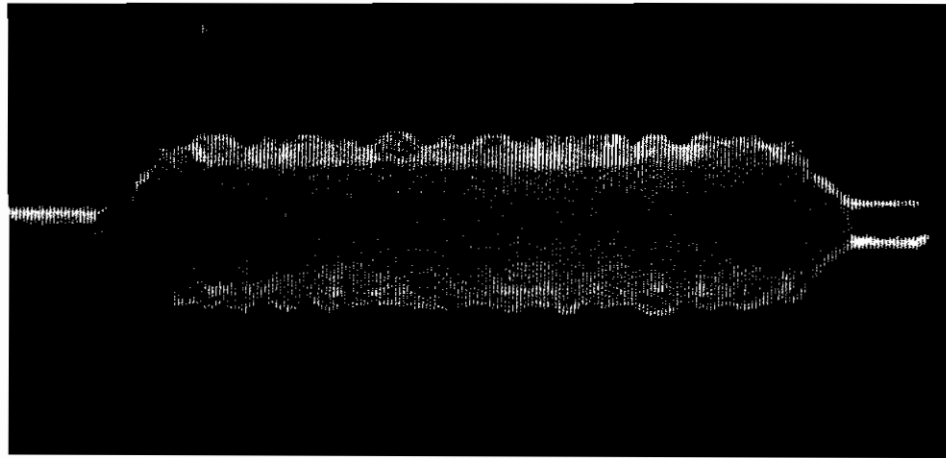
22. In 2012, total Medicare and Medicaid spending will exceed \$1 trillion, representing the largest category of federal spending, more than defense, social security and debt service. Medicare and Medicaid are also one of the largest purchasers and reimbursers of prescription devices in the country.

23. In addition, the Department of Veterans Affairs, the Department of Defense's TRICARE program, and the Federal Employees Health Benefit Plan each purchase and reimburse prescription devices with funds provided by the United States. All of these programs pay for surgical procedures which have employed Relieva Stratus MicroFlow Spacers.

24. The programs identified above spend billions of dollars each year on prescription drugs and devices. Not surprisingly, in order to prevent waste, fraud and abuse, the federal programs restrict the types and uses of devices that may be reimbursed with federal funds. These regulatory schemes are designed to ensure that the federal and state programs only pay for devices which are found to be safe and effective for their prescribed uses. As is described below, the Defendants intentionally evaded these controls resulting in the federal government paying for ineffective sinus treatments that would never have been approved had the true facts been known.

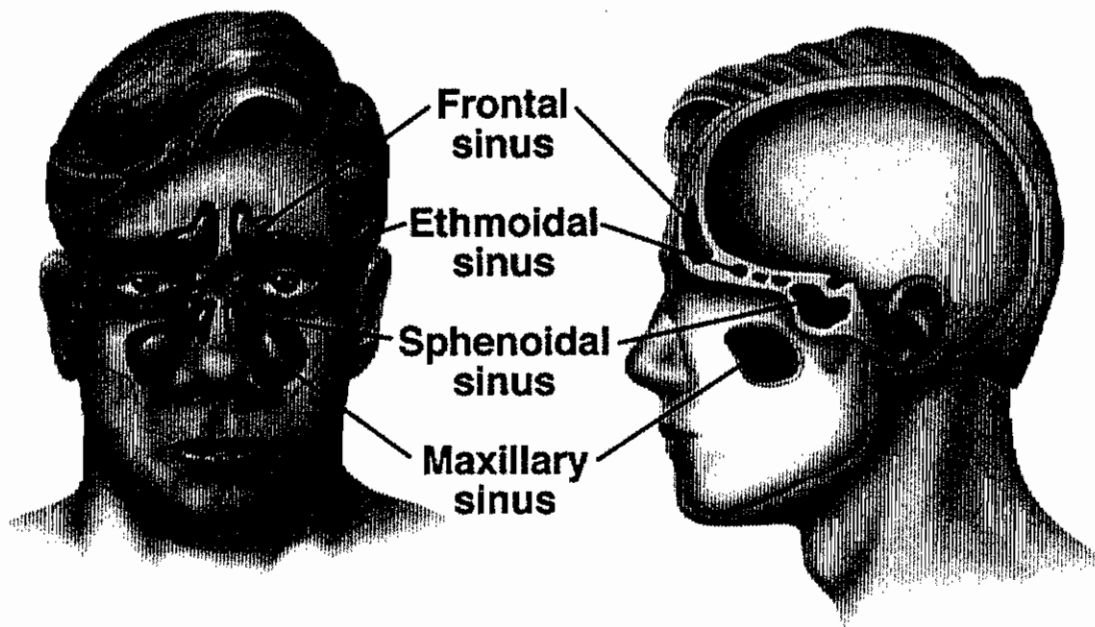
III. RELIEVA STRATUS MICROFLOW SINUS SPACER

25. The products that are the subject of this case include all types and generations of sinus spacers known as the Relieva Stratus MicroFlow Spacer (the “MicroFlow Spacer”). Sinus spacers are small, oblong objects that are capable of fitting snugly inside certain paranasal sinuses. Connected to the spacer are long, thin catheters to allow for insertion and removal, and a surrounding sheath which facilitates insertion and is removed immediately thereafter. Acclarent’s MicroFlow Spacers are actually hollow fluid reservoirs encapsulated with a shell containing tiny pores out of which fluid can seep. (See picture below).



26. The paranasal sinuses are four pairs of air-filled cavities located in the skull. They are extensions of the nasal cavity and are lined with nasal mucosal cells. Each sinus is named after the cranial bone in which it is located: maxillary, frontal, ethmoid, and sphenoid. (See following figure).

Sinuses



27. The sinuses secrete mucus that drains to the nose through a small opening, one for each sinus, called the *ostium*. Sinusitis refers to the inflammation of the sinuses, though the term rhinosinusitis is preferred because inflammation of the sinuses rarely occurs without concomitant and preceding inflammation of the nasal mucosa. Symptom duration further characterizes rhinosinusitis. Patients with symptoms that have lasted less than 4 weeks have acute rhinosinusitis (“ARS”); those with symptoms between 4 and 12 weeks have subacute rhinosinusitis; and those with symptoms lasting more than 12 weeks have chronic rhinosinusitis (“CRS”). Patients with four or more episodes of ARS within a year with symptom-free intervals have recurrent acute rhinosinusitis.

28. Viral infection cause most cases of ARS. The combination of mucosal inflammation and thickened, insufficiently cleared nasal secretions causes sinus obstruction. This, in turn, leads to mucous buildup in the sinuses, which causes pain and pressure and can

become secondarily infected. ARS is usually self-limiting, and treatment is focused on symptom relief. Options include non-steroidal anti-inflammatories and acetaminophen for pain relief, nasal irrigation with saline, topical glucocorticoids and decongestants. Antibiotics may be warranted if symptoms do not resolve within two weeks or are suggestive of a bacterial etiology (*e.g.*, fever). Surgery is not indicated for ARS.

29. CRS is an inflammatory condition of the paranasal sinuses and nasal passages that lasts greater than 12 weeks. Therapy is geared towards achieving four goals:

- Controlling mucosal inflammation and edema;
- Maintaining adequate sinus drainage;
- Treating any underlying infection; and
- Reducing the number of acute exacerbations.

Available medical therapies include nasal irrigation with saline, intranasal glucocorticoids (*i.e.*, nasal steroid sprays), and nasal glucocorticoid instillations (*i.e.*, nasal steroid drops that are instilled in a nostril and with patient positioning enter the sinuses). In severe cases, oral glucocorticoids are used, and antimicrobials may be necessary if there is an infection.

30. Since CRS is an inflammatory disorder, medical intervention should precede any surgical intervention. Yet, surgery is indicated in cases where, for example, symptoms persist despite intensive medical therapy, surgery is needed to restore sinus ventilation or clear nasal polyps, or in cases where the disease has extended beyond the sinus cavities. Traditional surgeries involved extranasal and invasive approaches. Functional endoscopic sinus surgery (“FESS”) is a more recent, minimally invasive procedure that removes anatomical and pathological sinus obstructions, thus restoring sinus ventilation. A third surgical technique—Acclarent’s balloon sinuplasty (“BSP”)—is even more recent and mimics the treatment of a

clogged coronary artery. As with balloon angioplasty, BSP involves inflating a balloon positioned in the blocked ostium to relieve obstruction. No randomized controlled trials comparing the efficacy of BSP with FESS exist. With BPS, a physician cannot obtain a tissue culture. Thus, concurrent or follow-up FESS may be necessary.

31. Acclarent has developed two models of spacer. One is the Relieva Stratus MicroFlow Frontal Spacer, catalogue number BC1417RS, which is designed to be inserted into the frontal sinus. The other is Relieva Stratus MicroFlow Ethmoid Spacer, catalogue number BC1017RS, which is designed to be inserted into the ethmoid sinus. Earlier versions of the latter product may have been referred to simply as the Ethmoid Sinus Spacer.

IV. THE MICROFLOW SPACER'S INTENDED USE

32. Acclarent has stated to the FDA that the MicroFlow Spacers' intended use is as a "postoperative spacer," presumably after sinus surgery involving Acclarent's main product line known as Balloon Sinuplasty™. The goal of a spacer is to maintain an opening in the ethmoid and frontal sinuses within the first 14 days following surgery. The theory is that a spacer will maintain a distance between the opposing walls of the sinus, thereby preventing adhesions or obstructions caused by the tissue growing together.

33. These statements were false. Acclarent never intended for the MicroFlow Spacers to be mere spacers and passive healing aids. To the contrary, even before the products were cleared by the FDA, Acclarent had intended the MicroFlow Spacers to be—as their name suggests—drug delivery devices. Specifically, Acclarent's intended use for the MicroFlow spacers was to have its reservoir filled with injectable corticosteroid known as Kenalog-40.

34. Kenalog-40 is suspension formulation of triamcinolone acetonide. Kenalog-40 is indicated for injectable corticosteroid therapy, either intramuscular (deep inside muscle tissue),

for such conditions as allergies, leukemias, lymphomas, *etc.*, or intra-articularly (inside joints) for such conditions as acute gouty arthritis, bursitis, rheumatoid arthritis, *etc.* Kenalog-40 was never approved for topical use, use in the paranasal sinuses, or to for topical delivery through a sinus spacer. Thus any marketing of Kenalog-40 for such purposes was off-label marketing.

35. Moreover, Kenalog-40 is not recommended for periocular use, because various eye problems including exophthalmos, glaucoma, increased intraocular pressure, posterior subcapsular cataracts, and rare instances of blindness have been associated with periocular injections. Acclarent disregarded these warnings and risks and recommended off-label use of Kenalog-40 in the frontal and ethmoid sinuses, both of which are periocular. Kenalog-40 contains a specific warning against intraocular administration or administration into the nasal turbinates. Acclarent disregarded this warning by recommending suturing of the sinus spacers to the nasal turbinates to hold them in place, which increased the chance that Kenalog-40 could enter the turbinates.

36. The intended use of filling the MicroFlow spacer with Kenalog-40 is clearly set forth in documents that substantially pre-date the FDA clearance and introduction of the product into commerce. In fact, on or about April 9, 2007—more than a year before the first 510(k) clearance and product launch—Acclarent submitted to the United States Patent and Trademark Office sample instructions for use telling doctors, when using the spacer, to “Use only Kenalog-40 Injection.” The instructions then told physicians how to “prepare Kenalog-40 just before use,” specifically advising them to “shake the vial before use to ensure uniform suspension.” Nowhere did the instructions permit or discuss the use of saline instead of Kenalog-40.

37. These instructions were submitted in connection with application number 20080287908, Acclarent’s application for a patent titled “Ethmoidotomy System and

Implantable Spacer Devices Having Therapeutic Substance Delivery Capability for Treatment of Paranasal Sinusitis.” This patent claimed a method of using a sinus spacer that released Kenalog-40, and use of Kenalog-40 was one of the patent’s preferred embodiments. Moreover, in several other patents all filed between 2004 and 2007, well prior to the product launch, Acclarent discussed the use of devices that could deliver Kenalog-40’s active ingredient—triamcinolone acetonide—into the paranasal sinuses. These patents included U.S. Patent Nos. 7,654,997, 7,361,168, 7,462,175, 7,410,480, 7,419,497, 7,727,186, 7,500,971, 7,727,226, 7,645,272, 7,641,644, and 7,785,315.

38. On or about April 28, 2008, Acclarent filed a trademark application with the United States Patent and Trademark Office seeking to trademark the phrase “Relieva Stratus.” In the trademark application, Acclarent described the goods with which “Relieva Stratus” would be introduced into commerce as “sinus drug delivery devices.”

39. Acclarent trained its sales representatives to tell doctors that the MicroFlow spacers were specifically designed for use with Kenalog-40. In fact, Acclarent employees knew and privately admitted that saline solution would leak out of the spacer quickly in a matter of hours or days, thus rendering pointless the insertion of the spacer for even 14 days. The same problem applied to any drug of similar viscosity, including antibiotic drugs and most formulations of corticosteroids. The lone exception was Kenalog-40, a suspension formulation of triamcinolone acetonide, whose viscosity was intended to maximize the time that the drug remained in the injection area. Out of all of the available drug therapies, Kenalog-40 was the only therapy ever contemplated for use with the MicroFlow Spacer because of its viscosity. If less viscous drugs or fluids such as saline were intended, Acclarent would have designed smaller micro-pores.

40. Use of the spacers with Kenalog-40 is also the only use that Acclarent has ever investigated in living human beings (as opposed to cadavers). For example, Acclarent conducted “Clinical Evaluation of the Ethmoid Sinus Spacer (SPACER),” an open-label study of 14 patients. (CPR02082, Study NCT01054703). Acclarent also conducted “Clinical Study of Safety and Efficacy for the Relieva Stratus with Elution of Triamcinolone Acetonide (DELIVER),” an open-label study of 62 patients. (CPR005003, Study NCT00791934).

41. And the only use of Acclarent’s spacers described in articles published in medical journals is with Kenalog-40. This includes the following articles:

- Catalano, Thong, Garg, *The MicroFlow Spacer: A drug-eluting stent for the ethmoid sinus*, Operative Techniques in Otolaryngology - Head and Neck Surgery, June 2009 (Vol. 20, Issue 2, Pages 108-113).
- Melroy, Kuhn, *Safety of Ethmoid Drug-Eluting Catheter Insertion*, Annals of Otology, Rhinology & Laryngology, October 2009 (Vol. 118, Issue 10, Pages 708-713).

42. The Relator is not aware of any articles published by Acclarent or any physicians on behalf of company that discussed or recommended use of the MicroFlow spacer with saline solution or with no fluids whatsoever.

V. ACCLARENT IMPROPERLY EVADES PRE-MARKETING APPROVAL FOR THE MICROFLOW SPACER

43. Acclarent concealed the MicroFlow Spacer’s true intended use of drug-delivery from the FDA and instead submitted false statements omitting any reference to Kenalog-40 or drug delivery in order to obtain 510(k) marketing clearance. This occurred no fewer than four separate times with the following four distinct 510(k) clearances: Ethmoid Sinus Spacer

(K062458), Sinus Spacer (K072891), MicroFlow Spacer—Frontal (K083574), and MicroFlow Spacer—Ethmoid and Frontal (K093594).

44. Acclarent obtained these clearances by stating that MicroFlow Spacers “were substantially equivalent” to prior cleared devices, none of which were capable of or were intended for drug delivery. These predicate devices included the Rains Frontal Sinus Stent (K951066, Smith & Nephew—04/04/1995), the Micromedics, Inc. Sphenoid Sinus Stent (K050340, Micromedics—04/27/2005), and the Shikani Middle Meatal Antrostomy Stent (K912418, Micromedics—12/20/1991). The intended uses for these devices were to: “use as a postoperative stent to maintain an opening to the sphenoid sinus during the first 14 days following sinus surgery” and “provide for ventilation and drainage of fluids from the sphenoid sinus and helps prevent obstruction by adhesions.” These devices were not drug-delivery devices, and there were no references to their use with saline or Kenalog-40 and certainly no such instructions.

45. Any statement claiming that MicroFlow Spacers were “substantially equivalent” to these predicates was false and misleading because the MicroFlow Spacers had a different design that allowed for drug delivery and Acclarent’s intended use was for Kenalog-40 to be the drug that was delivered. This was the true intended use before and after FDA clearance. Acclarent markets the MicroFlow Spacer as a “drug-eluting stent” that is temporarily implanted into a sinus cavity to deliver topical Kenalog-40 for approximately thirty days in order to treat inflammatory sinus disease after balloon sinuplasty is performed using one of its products. Acclarent designed the device for that purpose and repeatedly informed its sales staff that it should be used for that purpose. However, neither the MicroFlow Spacer nor Kenalog-40 is approved for this usage. And in fact, Defendants are aware that the device does not work for this

use or even its labeled use. Defendants are also aware that the device is not medically necessary for any purpose and have therefore intentionally evaded efficacy review by the FDA.

46. The reason for evading an efficacy review was simple: Acclarent would not have been lawfully able to market the MicroFlow Spacers otherwise. Unlike prescription drugs, sponsors of prescription medical devices do not necessarily have to establish the safety and efficacy of a new medical device to the satisfaction of the United States Food & Drug Administration before a device may be legally marketed. Devices can avoid premarket approval if the sponsor can demonstrate to the FDA the device is a Class I or II device and that the device is substantially equivalent to another device legally marketed in the United States. To establish “substantial equivalence,” the sponsor must submit a Section 510(k) application to the FDA which establishes that the new device: (1) has the same intended use as a predicate device; and (2) the device has either (a) the same technological characteristics as the predicate, or (b) does not raise new questions of safety or efficacy and demonstrates that the new device is at least as safe and effective as the old device. In order to obtain Section 510(k) clearance, the device must have the same intended use as an existing, legally marketed device. If it does not, the manufacturer must obtain premarketing approval, which requires submission to the FDA of controlled clinical trials that establish the safety and efficacy of the device.

47. Of course, Acclarent knew that the MicroFlow Spacers did not have the same intended use as their predicates, which were not intended to deliver drugs at all. Acclarent also knew that MicroFlow Spacers had different technological characteristics, because their internal reservoir and micro-pores allowed for drug release, something the predicates lacked. Finally, Acclarent knew that a novel use of a paranasal spacer in combination with off-label Kenalog-40 would raise new safety and efficacy issues, which at a minimum would require a PMA for the

spacer, and perhaps also an sNDA for Kenalog-40. Neither a PMA nor an sNDA would be triggered, however, if the FDA were deceived into thinking that the MicroFlow Spacers were substantially equivalent to prior-cleared products such as the Rains Frontal Sinus Stent. This is why Acclarent, and later J&J, lied to the FDA about how the MicroFlow Spacers would be used and concealed their true intended use with Kenalog-40.

48. The fraudulent scheme worked: the FDA cleared various versions of the MicroFlow Spacer in March 2008, October 2008, January 2009, and March 2010. No PMA was ever required. Acclarent was thus able to launch the ethmoid spacer in the third quarter of 2008, and the frontal spacer in the first quarter of 2009.

VI. AFTER DECEIVING THE FDA INTO CLEARING THE MICROFLOW SPACER, ACCLARENT IMPROPERLY MARKETS THE DEVICE

49. Once Acclarent had received clearance to market the MicroFlow Spacer, it confronted the issue of how to encourage hospitals and physicians to purchase it. The MicroFlow Spacer, like many other medical devices, was not separately reimbursable under Medicare and the various state Medicaid programs and most private insurance programs. Most surgical procedures, including out-patient procedures which would use the MicroFlow Spacers, are reimbursed by public and private insurers on a procedural basis—the hospital or facility which performs the procedure receives a lump sum payment which covers the cost of the procedure including all of the surgical equipment used in the procedure. Under such reimbursement schemes adding additional expensive surgical equipment to the procedure, such as the placement of sinus spacers such as the MicroFlow Spacers, would not increase reimbursement but rather would reduce the net amount the hospital or facility received. To make the product's use economically feasible, Acclarent had to figure out how users could be reimbursed for the use of the MicroFlow Spacer. It selected reimbursement fraud.

50. Acclarent could have applied for a specific HCPCS billing code for the placement of MicroFlow Spacers. The Center for Medicare and Medicaid Systems (“CMS”), the federal agency that administers Medicare and Medicaid has a program for providing billing codes (known as “C” codes or “pass-through” codes) for new medical devices. The pass-through program is specifically designed so that hospitals can be reimbursed for using innovative and efficient medical devices, and permits institutions to be properly compensated for adopting the most up to date technology. However, to qualify for pass-through status, the applicant for such a code must establish that the device will “substantially improve the diagnosis or treatment of an illness or injury. . . compared to the benefits of a device or devices in a previously established category or other available treatment.” 42 C.F.R. § 419.66(c)(2). CMS requires clinical trial data to establish that the device constitutes a “substantial improvement” over other available treatment, and Acclarent had no such data for the MicroFlow Spacer. The device could not qualify for pass-through status and Acclarent knew it could not qualify.

51. Acclarent nonetheless recognized that if hospitals and ambulatory care centers did not receive increased reimbursement, they would not order or use MicroFlow Spacers. Although Acclarent acknowledged internally that the device was a surgical supply or a surgical tool, it informed its customers that they would receive maximum reimbursement if the removable device was coded as an “implant.” The device did not qualify as an “implant” procedure, since such procedures were for devices that were supposed to be inserted for more than thirty days and the MicroFlow Spacer was only cleared for use up to 14 days. Moreover, Defendants never possessed clinical data that showed that the device was safe if left in a sinus for more than 14 days. Similarly, it never possessed clinical data that the device had any efficacy after 14 days, even when used off-label with Kenalog-40.

52. Nonetheless, Acclarent informed its customers that the most profitable way to use the MicroFlow Spacer was to treat and code it as an implant. The customers took Acclarent's advice and submitted improper claims to Medicare and Medicaid claiming reimbursement for "implants," notwithstanding the fact the device was in actuality a removable surgical supply or surgical tool which did not qualify for additional reimbursement. Each such claim constituted the presentation of false claims, and such claims would not have been presented to the United States but for the actions of the Defendants.

53. Selling the device as an implant that was supposed to be inserted for 30 days had another advantage for Acclarent's customers. When surgeons are reimbursed for surgical procedures, including procedures relating to the frontal or ethmoid sinuses, they receive a single payment which is supposed to cover all follow up visits with the patient within a specified number of days of the surgery, often 14. This period is known as the "global window." Accordingly, a surgeon who removed a MicroFlow Spacer within the global window could not obtain additional compensation for an office visit to remove the device from the patient's sinus. However, if the surgeon treated the removable device like an implant and removed it thirty days or more from insertion, the removal date would likely be outside the global window and the surgeon would be able to separately charge for the removal visit. This would allow the surgeon to obtain additional compensation for the same amount of work, even though that work was intended to be covered under the institution's original reimbursement for the procedure.

54. Separate billing for an office visit was medically unnecessary because there was no reason to leave the MicroFlow Spacers in place for more than 14 days except to unjustly enrich the physician at the expense of a payor. Yet, by informing physicians that the MicroFlow Spacer should be treated (and billed) like an implant instead of a surgical supply or tool, the

Defendants caused Medicare and Medicaid to bill for unnecessary doctor's visits to remove the MicroFlow Spacers. Each additional surgical visit paid for by Medicare, Medicaid or any federal payor constituted the presentation of a false claim to the United States. Defendants caused each and every such claim.

55. When Acclarent began to market the MicroFlow Spacers in 2008, it trained its sales force to educate physicians to use the device with Kenalog-40 instead of saline. The sales force was told that saline drained out of the device immediately rendering the device useless. (Of course, Acclarent never revealed this fact to the FDA). Saline did not remain in the spacer for 14 days, much less 30 days. Acclarent specifically told its sales team that the device did not work with saline, that the device was designed to be used with a suspension drug, and to give the device the best chance to succeed, it should be used with Kenalog-40. Indeed, there is no evidence that Acclarent ever conducted any clinical trials with saline. The fact that the device's manufacturer never tested the device with the only liquid approved for use with the device is further evidence that the device was never intended by its manufacturer to be used as labeled, and that the device is misbranded.

56. After receiving the training instructions, the Relator and the rest of the Acclarent sales force detailed the device to physicians by insisting that it be used with Kenalog-40. The Relator was one of the leading salespersons for MicroFlow Spacers in the entire country and not one of her customers used the device with saline. Based on communications with other sales representatives from other regions, and from her attendance at national and regional sales conferences for Acclarent, the Relator learned that that her physicians' failure to use the device with saline was representative of the way physicians used the device around the country. No sales representatives marketed the device in accordance with its labeling; almost no physicians

used the device in accordance with its labeling; and the vast majority of physicians used Kenalog-40 off-label in conjunction with the device.

57. When the device was initially being marketed, Acclarent sales representatives, including the Relator, informed physicians that before-and-after CT scans of the sinus passages would demonstrate that the device was working. Acclarent sales representatives claimed that after the spacers were inserted, patients' Lund-Mackay scores, which could be determined from the CT scans, decreased. Indeed, Acclarent sponsored a clinical trial which was supposed to establish the efficacy of using the MicroFlow Spacers with Kenalog-40 to treat sinusitis. That trial called for comparing patients' Lund-Mackay scores before and after insertion of the MicroFlow Spacers. At least one of the Relator's customers was an investigator for this study. Other Acclarent customers were not formally enrolled in the study but performed CT sinus scans just to get a sense of whether using the product with Kenalog-40 actually worked.

58. No later than June 2009, less than a year from the launch of the MicroFlow Spacer, the Relator was informed that the customer who was participating in the clinical trial reviewed his patients' Lund-Mackay scores, but there was no improvement. Relator learned of similar reports from other sales representatives whose physicians performed CT scans. The other sales representatives confirmed that their doctors had performed CT scans and found no improvement in their patients. This testing by numerous physicians across the country was important evidence that the MicroFlow Spacers and Kenalog-40 did not improve patients' conditions and that the treatment of ineffective.

59. The negative Lund-Mackay scores drove Acclarent to remove that as a primary outcome in a clinical trial that was being conduct called the DELIVER Study. That trial, called "Safety and Efficacy for the Relieva Stratus with Elution of Triamcinolone Acetonide," was an

uncontrolled study “intended to evaluate the safety and efficacy of treating the ethmoid sinuses with the Ethmoid Sinus Spacer and Access System used for the local delivery of Kenalog-40, over a period of 28 days.” This study was supposed to show that the off-label use of MicroFlow Spacer with Kenalog-40 was effective. And when the trial was started in August 2008, the primary outcome measure original was improvement in sinus CT Lund-Mackay scores. However, one year into the trial, the trial’s primary outcome was abruptly changed to “Safety as assessed by the occurrence of adverse events,” and Lund-Mackay scores no longer were the primary outcome. The principal investigator, Dr. Kuhn, resigned from the study shortly after. Acclarent has never publicly disclosed the reason for the changes, nor has it published the negative results of the Lund-Mackay scores.

60. Knowing that its doctors were not seeing improvements in their patients conditions (and also aware that no one else had access to this data), Acclarent had a duty to make its customers aware of these test results, particularly in light of its off-label promotion of the MicroFlow Spacers and Kenalog-40. Acclarent, however, continued to suppress the truth regarding the efficacy of MicroFlow Spacers and Kenalog-40. Instead of instructing the sales representative to provide accurate information regarding the clinical testing results, Acclarent informed the sales representatives that they should no longer recommend physicians obtain Lund- Mackay scores, since such testing would expose that the device did not work.

61. MicroFlow Spacers are only cleared to be used in the frontal and ethmoid sinuses. Acclarent, however, trained its sales representatives to also promote the use of the spacers in the maxillary sinuses. Sales managers distributed reports of reps successfully convincing surgeons to use the device in the maxillary sinuses and advised sales representatives that they should emulate such successful sales techniques. Acclarent also trained its sales staff to recommend

that physicians insert as many spacers into the patient as possible. When billed as an implant, hospitals and institutions received more reimbursement for each spacer inserted. So, for example, if an institution received a \$1,000 profit for inserting two MicroFlow Spacers in the frontal sinuses, representatives were trained to promote to customers that their profit could be tripled if six spacers were inserted and spacers were also placed in the ethmoid and maxillary sinuses. Even if the surgeon conducted a sinuplasty in a single set of sinuses, representatives (falsely) informed doctors that it was appropriate to place MicroFlow Spacers in the sinuses that were unaffected by the procedure. As a result of such promotion, instances where four or six spacers were inserted in a single procedure became increasingly common and MicroFlow Spacer sales significantly increased. There was no scientific or medical support, however, for placing spacers in multiple sinus cavities, and the procedures where multiple MicroFlow Spacers were inserted were medically unnecessary.

62. Sales of the MicroFlow Spacers grew steadily from their initial market launch in mid-2008, through the introduction of the frontal sinus spacer in early 2009, until Acclarent's acquisition by the Ethicon division of Johnson & Johnson in January 2010. Shortly after the acquisition, Acclarent anticipated annual sales of MicroFlow Spacers to exceed \$30 million annually, of which no less than 20% was paid for by Medicare, Medicaid or other federal health insurance plans.

63. On January 20, 2010, Ethicon acquired Acclarent, and Johnson & Johnson management took over the day to day responsibilities for selling Acclarent products including the MicroFlow Spacers. Although, J&J and Ethicon management now oversaw Acclarent operations, Ethicon and J&J kept Acclarent as a separate division. Thus, the Acclarent sales

force continued to sell the same products as before the merger and the sales force reported to their former Acclarent managers.

64. On March 26, 2010 only two months after the acquisition, Defendants announced that the Acclarent division would no longer promote the MicroFlow Spacer in the United States. In the announcement, management stated that “the regulatory and enforcement environment around off-label use of products has changed over the last few years. Regulators are increasing their focus and attention on companies whose products are used off-label.” Defendants announced that they would also destroy all existing promotional material for the MicroFlow Spacer. Of course, the material they destroyed was off-label promotional material—there would have been no reason to destroy on-label promotional material. And Defendants refused to make any effort to promote the product on-label because they knew there was no market for such use. But despite knowing this fact, Defendants also refused to take the MicroFlow Spacer off the market. The product would remain available to existing customers as a “catalog” product. Sales representatives, such as the Relator, however, would still be compensated for their sales of the MicroFlow Spacer and the product would still count toward their sales quotas, though not fully.

VII. ACCLARENT FIRES THE RELATOR FOR TRYING TO HALT THE OFF-LABEL MARKETING OF THE MICROFLOW SPACER AND KENALOG-40

65. The Relator is an experienced medical device sales professional. She has been employed in the medical device industry continuously since 2001, and was a drug sales representative for several years before that. With prior companies, she has been a member of elite sales groups and been responsible for some of the largest sales of her prior employers. She joined Acclarent in June 2007 as an ENT Consultant. She was one of the first sales representatives trained to sell the MicroFlow Spacer and was one of the top sellers of the MicroFlow Spacers before Defendants stopped overt promotion of the product in March 2010.

66. When Defendants announced that there would be no further promotion of the MicroFlow Spacer, sales representatives were informed that their sales quotas would be adjusted and the entire amount of expected MicroFlow Spacer sales would be eliminated from their sales targets. In reality, this did not occur. The Relator's sales target were adjusted by only a small fraction of her MicroFlow Spacer sales, as were the quotas of her colleagues. Due to the fact that MicroFlow Spacer sales still counted towards sale targets, almost every Acclarent sales representative was unable to achieve their sales goal for 2010 without engaging in off-label promotion.

67. After a few months, sales managers realized that without sales of the MicroFlow Spacer, Acclarent's sales figures would be significantly lower. Sales managers began to put pressure on the sales representative to promote MicroFlow sales as they had done before the acquisition by Johnson & Johnson.

68. After Defendants announced that the MicroFlow Spacer would no longer be promoted by the sales force, the Relator stopped selling the product. After the announcement, the Relator was uncomfortable with off-label promotion of the device and was relieved to no longer sell the product, although she had been one of the product's top salespersons.

69. In July 2010, the Relator had a meeting with one of her superiors who told her that the company needed her to return to actively selling the MicroFlow Spacer to her customers. The Relator informed the official that she did not think it was right that the product be sold off-label and that she did not want to do it. The official told Relator that it was necessary for her to resume MicroFlow Spacer sales regardless of her desires and regardless of the fact that off-label promotion was illegal.

70. In August 2010, there was an area sales conference for the Relator's sales area. She was told that personnel from the regulatory division of the company would be present at the first day, but they would not be present on the second day, and therefore on the second day Acclarent sales managers planned to take advantage of the absence of regulatory personnel to off-label marketing of the MicroFlow Spacer. Specifically, sales personnel wanted to discuss at length the need to promote MicroFlow Spacer purchases in the manner they had previously been promoted and in derogation of the Defendants' official position that the product was only a catalog item. Knowing that she would be placed under substantial pressure to sell the MicroFlow Spacer off-label, on the first day of the conference, Relator conspicuously posed numerous questions to the regulatory personnel about how to handle inquiries from physicians about the MicroFlow Spacer and what could specifically be said about the MicroFlow spacers on any calls to customers. The regulatory officials were concerned about the Relator's numerous questions about sales of the MicroFlow Spacer and decided to change their plans and stay an extra day to address the concerns about the product. Because the regulatory officials stayed an extra day, neither the area sales manager, the regional sales manager, nor the Director of Training were able openly discuss their plans to renew MicroFlow Spacer promotion and sales. The sales managers were furious at the Relator for preventing them from discussing their new plan to promote the MicroFlow Spacer.

71. Within 30 days of the area sales meeting, the Relator was put on an unrealistic performance plan, and by January 4, 2011, she was terminated. Relator's sales of products were still good despite the fact that the number of physicians in her territory had been drastically reduced without a comparable reduction of her sales goals. Although there was a history of friction between the Relator and her boss which was well known to sales management, senior

management had protected her, particularly the high level official who in July 2010 had insisted that she sell off-label. However, once the Relator refused to engage in off-label promotion of the MicroFlow Spacer, senior managers no longer took steps to protect her. They allowed Relator to be terminated because she would no longer engage in off-label promotion.

72. As a result of the retaliatory termination, Relator has suffered severe financial damage. Although Relator is currently employed, she was forced to take a job with significantly lower compensation and benefits. Relator's compensation has been reduced by approximately \$75,000 annually. She has also suffered emotional distress and other damages.

VIII. ACCLARENT HAS CAUSED AND IS CAUSING FALSE CLAIMS TO BE SUBMITTED FOR REIMBURSEMENT TO THE UNITED STATES

73. At all relevant times, the MicroFlow Spacer was misbranded in violation of the Food Drug and Cosmetic Act, 21 U.S.C. §352. At a minimum, each and every MicroFlow Spacer is misbranded because:

- The labeling for the device falsely states its intended purpose.
- The instructions for use are not adequate and are misleading.
- The device's labeling, including the promotional material created by Defendants to market the product, falsely state that the product is effective for the treatment of sinusitis and related sinus maladies when there is no clinical evidence as to the product's efficacy.

74. Misbranded devices may not be introduced into commerce and are not eligible to be purchased by Medicare, Medicaid or any other health insurance program funded by the United States. At all relevant times, Defendants have been aware that the federal government was the ultimate purchaser of the numerous MicroFlow Spacers. Defendants knew the United States routinely paid hospitals for their use of MicroFlow Spacers. Thus, Defendants knew that Medicare would receive numerous claims for reimbursement for their misbranded products. Defendants were also aware that Medicare and all other federally funded programs were not

supposed to pay for misbranded products. Consequently, every claim presented to Medicare (or any other health care program financed by the federal government) for a MicroFlow Spacer was a false claim, and each claim was knowingly caused by Defendants.

75. Each of the Defendants was also aware that Medicare and Medicaid do not pay for devices or drugs that are used off-label. At all times, Defendants knew that the MicroFlow Spacer was to be used off-label and it was specifically designed to be used off-label. Indeed, Defendants openly discouraged the use of the product on-label and when Defendants sought to reduce the visibility of the off-label promotion of the product in March 2010, they recognized that there was no legitimate way to promote the product on-label. By deliberately promoting a product that was designed to be used off-label, Defendants knowingly caused the presentation of false claims to the United States.

76. Each of the Defendants was also aware that when the product was used as intended by Acclarent, the MicroFlow Spacer would be used to deliver Kenalog-40 to the sinus passages. Defendants knew that this was an off-label use of Kenalog-40, which is not approved for use in the sinuses, nor approved for topical or inter-nasal usage. By promoting the MicroFlow Spacer to be used with Kenalog-40, Defendants knew that they were causing Kenalog-40 to be prescribed off-label, and that the same federal programs that purchased the MicroFlow Spacer would also purchase off-label Kenalog-40. Because Kenalog-40 as used in the MicroFlow Spacer is not a "qualified outpatient drug" it is not eligible for reimbursement by Medicare or Medicaid. Defendants, however, knew that their promotion of the MicroFlow Spacer would directly result in the presentation of false claims to the United States for the purchase of Kenalog-40.

77. Additionally, Defendants were aware that both Medicare and Medicaid only reimburse devices that are medically necessary. Defendants were aware there was no medical justification for using the MicroFlow Spacer pursuant to its approved Instructions For Use because saline flowed out of the spacer in a short period of time and therefore could not keep the affected areas moist. Defendants also knew there was no scientific basis for using the MicroFlow Spacer with Kenalog-40. Defendants have conducted no controlled clinical trials with Kenalog-40 and the MicroFlow Spacer that establish that it provides any medical benefit. Indeed, commencing in 2009, Defendants began receiving results from the DELIVER clinical trial, as well as anecdotal reports from physicians using the product, that Kenalog-40 did not reduce Lund-Mackay scores. These reports established that the MicroFlow Spacer had no clinical benefit. Further, insufficient safety data exists regarding Kenalog-40's use in the sinuses and whether this corticosteroid can be delivered locally without side effects. By causing sales of a device that Defendants knew had no clinical benefit, Defendants have caused the presentation of numerous false claims.

78. Other medically unnecessary claims were caused by Defendants' promotion of the MicroFlow Spacers in the maxillary sinuses, where they are not approved, and for the insertion of multiple spacers including the placement of spacers in sinus cavities where there where no surgical or sinuplasty procedures had occurred. The indiscriminate use of spacers merely because Medicare, Medicaid, and the other federal payors will reimburse physicians for spacer insertion when multiple claims are presented for payment, is not justifiable and is an abusive practice with no medical basis. Encouraging physicians to insert multiple spacers merely because they can increase their reimbursements for procedures directly leads to the presentation of false claims.

79. Additionally, Defendants caused Medicare, Medicaid and the other federal insurance plans to pay for numerous unnecessary office visits. By convincing surgeons that the MicroFlow Spacer was not a surgical tool but was rather an “implant” that had to remain in place for 30 days, surgeons who inserted the device were able to bill for an additional medical visit when patients returned to the surgeon’s offices to have the spacers removed. There was no medical benefit to keeping the spacers in place for more than 14 days. By treating the spacers as if they were “implants,” however, the removal visits were not considered ordinary surgical follow up visits and the surgeons were permitted to obtain reimbursement from the federal payors. Had Defendants instructed its customers to code the visits properly and to remove the spacers as set forth in the product’s “Instructions for Use,” the additional doctor visits would have never been presented to the federal payors or paid out of the federal fisc.

80. Defendants used numerous false statements to cause false claims to be submitted to Medicare, Medicaid and other federal payors. These false statements include:

- The MicroFlow Spacer should be used with Kenalog-40.
- Delivery of Kenalog-40 to the sinuses through the MicroFlow Spacer is a safe and effective treatment for sinusitis and other sinus maladies.
- Delivery of Kenalog-40 through the MicroFlow Spacer reduces patients’ Lund-Mackay scores.
- The MicroFlow Spacer can be properly reimbursed as an implant.
- The intended use of the MicroFlow Spacer is to keep sinus passages open after sinus surgery.

Each of these statements were used by the Defendants to market or distribute the MicroFlow Spacer and resulted in claims for the use of the spacer being submitted to Medicare, Medicaid

and other federal payment programs. The false statements set forth above were made to numerous physicians and surgeons, including but not limited to Dr. Thomas Kang and Dr. Jonathan Lara of the Carlson Ear Nose and Throat Associates in Tuscon, Arizona. The false statements were communicated to these physicians in December 2008. As a result of these false statements, Carlson Ear Nose and Throat Associates ordered and/or used numerous MicroFlow Spacers in their ENT procedures and regularly billed Medicare and/or Medicaid for their removal.

81. As a result of the Defendants' actions, thousands of false claims relating the MicroFlow Spacer, including unnecessary surgical procedures and office visits, have been presented and paid by the United States. An example of the types of claims were those submitted by Oro Valley Hospital, Oro Valley, Arizona, one of the Relator's largest purchaser of MicroFlow Spacers. Between December 2008 and November 2009, Oro Valley submitted no less than 10 claims to Medicare or Medicaid for MicroFlow Spacers, most of which were coded as implants. As a result of the number of MicroFlow Spacers ordered by this hospital, Acclarent declared the Oro Valley Hospital to be a Sinus Center of Excellence. Other hospitals in Relator's territory that submitted similar false claims during this time period include Banner Desert Medical Center, Mesa, AZ; Tempe St. Luke's Hospital, Tempe, AZ; Summit Healthcare Regional Medical Center, Show Low, AZ and the Mayo Clinic in Scottsdale, Arizona. Defendants' actions have resulted in the United States expending millions of dollars for false Medicare, Medicaid, and federal insurance claims that should have never been paid. As a result of the actions taken by the Defendants, numerous false claims were submitted to Medicare, Medicaid and other federal payors.

FIRST CAUSE OF ACTION
VIOLATION OF 31 U.S.C. §3729(a)(1)(A)

82. The Relator repeats and realleges the allegations set forth in paragraphs 1 through 81 above as though set forth herein.

83. As described in detail above, Defendants' actions have caused the presentation of numerous false claims to the United States through the Medicare and Medicaid programs and other federal health insurance programs. Defendants caused these claims to be filed by distributing, marketing and promoting a product it knew to be misbranded, by promoting the product knowing that it was not medically necessary, by promoting unnecessary and excessive utilization of the MicroFlow Spacer, and by coaching its customers to improperly code claims for the product, as well as through the other methods described above.

WHEREFORE, Relator, on behalf of the United States of America, requests that this Court:

- (a) Enter judgment holding Defendants liable for a civil penalty of \$11,000 for each violation of the False Claims Act committed by them;
- (b) Enter a judgment against Defendants for three times the amount of damages sustained by the United States because of the their acts;
- (c) Award the Relator a percentage of the proceeds of the action in accordance with 31 U.S.C. § 3730;
- (d) Award the Relator her costs and reasonable attorneys fees for prosecuting this action; and
- (e) Enter such other relief which the Court finds just and equitable.

SECOND CAUSE OF ACTION
VIOLATION OF 31 U.S.C. §3729 (a)(1)(B)

84. Relator repeats and realleges all of the allegations set forth in paragraphs 1 through 83 as though set forth herein.

85. In the regular course of its marketing, Defendants made the false statements identified in this Complaint. The statements were made for the purpose of causing hospitals and other institutions to buy, and physicians to use, the MicroFlow Spacer for patients who were covered by the Medicare program, the Medicaid program, and the other federally funded health insurance programs. Defendants were also aware when they made those statements that Medicare, Medicaid, and the other federal programs would reimburse the hospitals and other health institutions for their purchase of the MicroFlow Spacers. Defendants knew that their false statements regarding the MicroFlow Spacer would result in the submission and the payment of false claims.

86. Defendants' false statements were also material. Had Defendants informed the hospitals and physicians of the truth of the statements, the hospitals would not have continued to purchase, and the physicians would not have continued to prescribe, the MicroFlow Spacers. Had the United States known the truth regarding the false statements, it would have never permitted the federal programs to reimburse procedures or office visits relating to the MicroFlow Spacer.

87. As a result of the false statements, millions of dollars were spent by Medicare, Medicaid, and the other federal programs for MicroFlow Spacers and related procedures and visits that should have never been reimbursed.

WHEREFORE, Relator, on behalf of the United States of America, requests that this Court:

- (a) Enter judgment holding Defendants liable for civil penalties of \$11,000 for each violation of the False Claims Act;
- (b) Enter a judgment against Defendants for three times the amount of damages sustained by the United States because of their acts;
- (c) Award the Relator a percentage of the proceeds of the action in accordance with 31 U.S.C. § 3730;
- (d) Award the Relator her costs and reasonable attorneys fees for prosecuting this action; and
- (e) Enter such other relief which the Court finds just and equitable.

THIRD CAUSE OF ACTION
VIOLATION OF 31 U.S.C. §3730(h)

88. Relator repeats and realleges each of the allegations set forth in paragraphs 1 through 87 as though set forth herein.

89. As an employee of Acclarent, Relator had a right to gather information relating to false claims caused by Acclarent and to submit information regarding those claims to the United States. Employee also had a right to refuse to engage in behavior which would result in the presentation of false claims to the United States and to refuse to engage in off-label promotion.

90. Defendant retaliated against Relator, and ultimately fired her because the Relator refused to engage in off-label promotion and attempted to stop practices that led to the presentation of false claims to the United States. Any other ground for dismissing or disciplining the Relator is pretextual. Accordingly, Defendants discharged, harassed, and discriminated against the Relator on account of conduct protected by 31 U.S.C. § 3130(h). Such conduct constitutes retaliatory conduct in violation of said statute. As a result of the Defendants'

wrongful retaliatory conduct, Relator has suffered substantial financial losses and suffered substantial emotional distress.

WHEREFORE, Relator, on her behalf, requests that this Court:

- (a) Reinstate Relator with the same seniority status that she would have had but for the discrimination;
- (b) Award the Relator two times the amount of back pay she would have earned but for the retaliation, and interest on that award;
- (c) Award the Relator compensation for all special damages she has sustained as a result of Defendant's discrimination;
- (d) Award the Relator her costs and reasonable attorneys' fees for prosecuting this action; and
- (e) Enter such other relief which the Court finds just and equitable.

FOURTH CAUSE OF ACTION
WRONGFUL TERMINATION IN VIOLATION OF PUBLIC POLICY

91. Relator repeats and realleges each of the allegations set forth in paragraphs 1 through 90 as though set forth herein.

92. The introduction of misbranded medical devices into interstate commerce and the misbranding and off-label promotion of any medical device which might cause serious personal injury constitute criminal violations of the Food, Drug & Cosmetic Act which are punishable by fine and/or imprisonment. Employees have a right to refuse to participate in such conduct or to report such conduct to the appropriate authorities, including the United States Food and Drug Administration. Employees also have a right to act in good faith to halt harm to the public and to try to prevent conduct that the employee believes will endanger the public. Any type of

disciplinary action or termination which is taken in retaliation for such protected conduct is against public policy and constitutes wrongful retaliation or termination.

93. The Relator, aware that the MicroFlow spacer was only being used off-label and served no legitimate medical purpose, could legally refuse to promote the misbranded device, and she could not be dismissed for taking actions that prevented the misbranded device from being further distributed in interstate commerce. Nor could Defendants take any retaliatory action against the Relator for such conduct. Yet, Defendants wrongfully, and in violation of public policy, terminated Relator solely because she refused to promote the misbranded MicroFlow Spacer.

94. Defendants' termination of the Relator was in violation of public policy and constitutes a wrongful termination. As a result of the wrongful termination, Relator has suffered substantial financial losses and suffered substantial emotional distress.

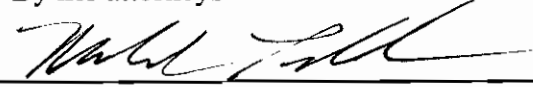
WHEREFORE, Relator, on her behalf, requests that this Court:

- (a) Reinstate Relator with the same seniority status that she would have had but for the retaliation;
- (b) Award the Relator the amount of back pay she would have earned but for the retaliation, the value of all commissions and benefits she would have earned, and interest on that award;
- (c) Award the Relator compensation for all special damages she has sustained as a result of Defendants' discrimination;
- (d) Award the Relator her costs and reasonable attorneys fees for prosecuting this action; and
- (e) Enter such other relief which the Court finds just and equitable.

Respectfully submitted

RELATOR MELAYNA LOKOSKY,
On behalf of the United States of America,

By her attorneys



Thomas M. Greene, Esq., BBO # 210020

tgreene@greenellp.com

Michael Tabb, Esq., BBO # 491310

matabb@greenellp.com

Ilyas J. Rona, Esq., BBO # 642964

irona@greenellp.com

GREENE LLP

33 Broad Street, 5th Floor

Boston, MA 02109

(617) 261-0040

Dated: July 8, 2011